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09/911,353	07/23/2001	Mark Dehdashtian	VAS-5644	3388

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EXAMINER
JACKSON, ANDRE K

ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 06/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/911,353	Applicant(s) DEHDASHTIAN ET AL.	
	Examiner Andre' K. Jackson	Art Unit 2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The proposed drawing correction filed on 04/01/03 has been disapproved because it is not in the form of a pen-and-ink sketch showing changes in red ink or with the changes otherwise highlighted. See MPEP § 608.02(v).

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not state that the person making the oath or declaration believes the named inventor or inventors to be the ***original and first*** inventor or inventors of the subject matter which is claimed and for which a patent is sought.

37 CFR 1.63. Oath or declaration.
(a) An oath or declaration filed under § 1.51(b)(2) as a part of a nonprovisional application must:
(1) Be executed, i.e., signed, in accordance with either § 1.66 or § 1.68. There is no minimum
age for a person to be qualified to sign, but the person must be competent to sign, i.e., understand
the document that the person is signing;
(2) Identify each inventor by full name, including the family name, and at least one given name
without abbreviation together with any other given name or initial;
(3) Identify the country of citizenship of each inventor; and
(4) State that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and
for which a patent is sought.
(b) In addition to meeting the requirements of paragraph (a) of this section, the oath or declaration must also:
(1) Identify the application to which it is directed;

(2) State that the person making the oath or declaration has reviewed and understands the contents of the application, including the claims, as amended by any amendment specifically referred to in the oath or declaration; and
(3) State that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in § 1.56.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1,2,4-7,9-12,17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer (5670708) in view of Dunkelman et al.

Regarding claim 1, Vilendrer discloses a "High frequency intravascular prosthesis fatigue tester" which has pre-tester with fixtures to couple the free ends of the tissue tube, a fluid supply in communication with at least one of the fixtures (Figure 6) and a stent. What is not disclosed by Vilendrer is an animal tissue tube. However, Dunkelman et al. disclose an "Apparatus and method for sterilizing, seeding, culturing, storing, shipping and testing tissue synthetic or native, vascular grafts" which uses an animal tissue tube (Abstract). Therefore, to modify Vildendrer to include an animal tissue tube as taught by Dunkelman et al. would have been obvious to one of ordinary skill in the art at the time of

the invention since while using animal tissue the user would be able to test the tissue through normal physiological functions of the human vascular system.

Regarding claim 4, Vilendrer discloses a pulsatile pumping system for fluid supply that pressurizes the tissue tube lumen to pressures found in the human vascular system (Column 6, 46-54).

Regarding claim 5, Vilendrer discloses a sensor for measuring the exterior diameter of the tissue tube (Column 6, lines 30-45).

Regarding claim 6, Vilendrer discloses where the sensor is non-contact sensor (Column 3, line 64).

Regarding claim 7, Vilendrer discloses where sensor is a laser micrometer (Column 4, line 9).

Regarding claim 9, Vilendrer discloses where sealingly coupling opposed free ends of a tissue tube onto fixtures of a tester/pre-tester (Figure 3), positioning a stent within the tissue tube (Figure 6, column 4, line 35) and providing a fluid to the tissue tube lumen via at least one of the fixtures (Column 4, line 36), a fluid supply in communication with at least one of the fixtures (Figure 6) and a stent. What is not disclosed by Vilendrer is an animal tissue tube. However, Dunkelman et al. disclose an "Apparatus and method for sterilizing, seeding, culturing, storing, shipping and testing tissue synthetic or native, vascular grafts" which uses an animal tissue tube (Abstract). Therefore, to modify Vildendrer to include

an animal tissue tube as taught by Dunkelman et al. would have been obvious to one of ordinary skill in the art at the time of the invention since synthetic grafts usually have inadequate patency rates for many uses.

Regarding claim 10, Vilendrer discloses pressurizing the fluid in the tissue tube lumen to pulsatile pressures found in the human vascular system (Column 2, 5-9).

Regarding claim 11, Vilendrer discloses measuring the exterior diameter of the tissue tube at different pressures (Column 6, line 54).

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer (5670708) in view of Dunkelman et al. as applied to claim 1 above, and further in view of Bier et al.

Regarding claim 2, neither Vilendrer nor Dunkelman et al. disclose where the animal tissue is porcine. However, Bier et al. discloses animal tissue that is swine, which is porcine. Therefore, since it is known to use animal tissue for testing as evidenced by Dunkelman et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vilendrer to include where the animal tissue is porcine since the tissue is close to human tissue.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer in view of Dunkelman et al. and Bier et al. as applied to claim 2 above, and further in view of Love et al.

Regarding claim 3, neither Vilendrer nor Dunkelman et al. disclose where the animal tissue is a section of porcine aorta with any side branches ligated. However, Love et al. discloses where the animal tissue is a section of porcine (Column 1, lines 33-40). Therefore, it would have been obvious to one of ordinary skill in the art to modify Vilendrer to include where the animal tissue is a section of porcine as taught by Bier et al. since tissue is in close characteristics to human tissue. Side branches are not disclosed but it would be within the purview of the skilled artisan to ligate the branches to prevent the any leakage.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer (5670708) in view of Dunkelman et al. as applied to claim 1 above, and further in view of Glenn et al.

Regarding claim 8, neither Vilendrer nor Dunkelman et al. disclose where the stented graft has multiple individual wires at axially spaced locations along the outer graft tube and where the sensor is positioned to measure the exterior diameter of the animal tissue tube at the axially spaced locations. However, Glenn et al. disclose where the stented graft has multiple individual wires at axially spaced locations along the outer graft tube and where the sensor is positioned to measure the exterior diameter of the tube at the axially spaced locations (Page 1, Introduction and page 2 Test methods). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vilendrer to

include where the stented graft has multiple individual wires at axially spaced locations along the outer graft tube and where the sensor is positioned to measure the exterior diameter of the animal tissue tube at the axially spaced locations as taught by Glenn et al. since this modification would provide an exact measurement of the diameter of the tube's diameter.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer (5670708) in view of Dunkelman et al. as applied to claim 9 above, and further in view of Glenn et al. (EnduraTec.com/papers/nitenol).

Regarding claim 12, Vilendrer discloses: recording data (12) on the measured exterior diameter of the tissue tube; sealingly coupling opposed free ends of a tissue tube onto fixtures of a tester (Figure 3); positioning a stent within the tissue tube (Figure 6, column 4, line 35); providing a fluid to the tissue tube lumen via at least one of the fixtures (Column 4, line 36); pressurizing the fluid in the tube lumen at a pulsed rate (Column 6, lines 45-54); and measuring the exterior diameter of the synthetic tube and controlling the fluid pressure based on the recorded data (Column 6, lines 4-19). Neither Vilendrer nor Dunkelman disclose a pre-test. However, Glenn et al. discloses an "Accelerated pulsatile fatigue testing on NI-TI coronary stents" which uses a pre-tester (Page 2, Test Methods). Therefore, it would have been obvious to one of ordinary skill in the art at

the time of the invention to modify Vilendrer to include a pre-tester as taught by Glenn et al. since this would help in compliance testing.

Regarding claim 13, neither Vilendrer nor Dunkelman et al. disclose where the fluid pressure in the synthetic tube is controlled to expand the diameter of the synthetic tube to the same dimension as the measured diameter of the exterior diameter of the animal tissue tube. However, Glenn et al. does disclose where the fluid pressure in the synthetic tube is controlled to expand the diameter of the synthetic tube to the same dimension as the measured diameter of the exterior diameter of the animal tissue tube (Page 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Vilendrer by using fluid pressure in the synthetic tube which is controlled to expand the diameter of the synthetic tube to the same dimension as the measured diameter of the exterior diameter of the animal tissue tube as taught by Glenn et al. since this would mimic the action of human arteries.

Regarding claim 14, Vilendrer discloses where the tube lumen is pressurized to both normal and abnormal pulsatile pressures found in the human vascular system and the synthetic tube lumen is pressurized at a pulsed rate based on the measured exterior diameter of the tissue tube to simulate both normal and abnormal compliance conditions (Column 6).

Regarding claim 15, neither Vilendrer nor Dunkelman et al. disclose pressurizing the fluid in the tube lumen to pulsatile pressures found in the

human vascular system and measuring the exterior diameter of the tube at the axially spaced locations and at different pressures. However, Glenn et al. disclose pressurizing the fluid in the tube lumen to pulsatile pressures found in the human vascular system and measuring the exterior diameter of the tube at the axially spaced locations and at different pressures (Page 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Vilendrer to include pressurizing the fluid in the tube lumen to pulsatile pressures found in the human vascular system and measuring the exterior diameter of the tube at the axially spaced locations and at different pressures as taught by Glenn et al. since this modification would give the tube an exact measurement of the diameter of the tube and mimic the action of human arteries.

Regarding claim 16, Vilendrer discloses: recording data (12) on the measured exterior diameter of the tissue tube; sealingly coupling opposed free ends of an tissue tube onto fixtures of a tester (Figure 3); positioning a stent within the tissue tube (Figure 6, column 4, line 35); providing a fluid to the tissue tube lumen via at least one of the fixtures (Column 4, line 36); and pressurizing the fluid in the tube lumen at a pulsed rate (Column 6, lines 45-54). Neither Vilendrer nor Dunkelman et al. disclose measuring the exterior diameter of the synthetic tube at the axially spaced locations while controlling the fluid pressure based on the recorded data such that the diameters of the synthetic tube at axially spaced locations expands to

the same dimensions as the measured diameter of the exterior diameter of the animal tissue tube at axially spaced locations. However, Glenn et al. disclose measuring the exterior diameter of the synthetic tube at the axially spaced locations while controlling the fluid pressure based on the recorded data such that the diameters of the synthetic tube at axially spaced locations expands to the same dimensions as the measured diameter of the exterior diameter of the animal tissue tube at axially spaced locations (Page 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vilendrer to include measuring the exterior diameter of the synthetic tube at the axially spaced locations while controlling the fluid pressure based on the recorded data such that the diameters of the synthetic tube at axially spaced locations expands to the same dimensions as the measured diameter of the exterior diameter of the animal tissue tube at axially spaced locations as taught by Glenn et al. since this modification would provide an exact measurement of the diameter of the tube and mimic the action of human arteries.

9. Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer in view of Glenn et al. (EnduraTec.com/papers/nitenol).

Regarding claim 17, Vilendrer discloses: recording data (12) on the measured exterior diameter of the tissue tube; sealingly coupling opposed

free ends of a tissue tube onto fixtures of a pre-tester (Figure 3); positioning a stent within the tissue tube (Figure 6, column 4, line 35); providing a fluid to the tissue tube lumen via at least one of the fixtures (Column 4, line 36); pressurizing the fluid in the tube lumen at a pulsed rate (Column 6, lines 45-54); and measuring the exterior diameter of the synthetic tube and controlling the fluid pressure based on the recorded data (Column 6, lines 4-19). Vilendrer does not disclose a separate tester and pre-tester. However, Glenn et al. uses the machine as a pre-tester (Page 2, Test Methods). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include pre-tester in the invention of Vilendrer since this modification would allow the user to test the stents at different settings using different machines.

Regarding claim 18, Vilendrer does not disclose where the fluid pressure within the tester tube is controlled to expand the diameter of the tester tube to the same dimension as the measured diameter of the pre-tester tube. However, Glenn et al. does disclose where the fluid pressure within the tester tube is controlled to expand the diameter of the tester tube to the same dimension as the measured diameter of the pre-tester tube (Page 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vilendrer to include where the fluid pressure within the tester tube is controlled to expand the diameter of the tester tube to the same dimension as the measured

diameter of the pre-tester tube as taught by Glenn et al. since this modification would ensure that the testing measurements are not flawed since the dimensions are the same.

Regarding claim 19, Vilendrer discloses where the tube lumen is pressurized to both normal and abnormal pulsatile pressures found in the human vascular system and the tester tube lumen is pressurized at a pulsed rate based on the measured exterior diameter of the pre-tester tube to simulate both normal and abnormal compliance conditions (Column 6). Vilendrer does not mention a pre-tester tube. However, Glenn et al. disclose the use of a pre-tester (Page 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vilendrer to include a pre-tester tube to pressurized to both normal and abnormal pulsatile pressures found in the human vascular system and the tester tube lumen is pressurized at a pulsed rate based on the measured exterior diameter of the pre-tester tube to simulate both normal and abnormal compliance conditions as taught by Glenn et al. since this modification would give the user a chance to keep the conditions of one instrument constant and vary the conditions of other instrument.

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer in view of Glenn et al. (EnduraTec.com/papers/nitenol) as applied to claim 17 above, and further in view of Dunkelman et al.

Regarding claim 20, neither Vilendrer nor Glenn et al. disclose where the tissue is animal tissue. However, Dunkelman et al. uses an animal tissue tube (Abstract). Therefore, to modify Vildendrer to include an animal tissue tube as taught by Dunkelman et al. would have been obvious to one of ordinary skill in the art at the time of the invention since while using animal tissue the user would be able to test the tissue through normal physiological functions of the human vascular system.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andre' K. Jackson whose telephone number is (703) 305-1522. The examiner can normally be reached on Mon.-Thurs. 7AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (703) 305-4705. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1782.

A.J.
June 2, 2003

HEZRON WILLIAMS
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